PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2004/027187	19.08.2004	20.08.2003

International Patent Classification (IPC) or both national classification and IPC
A61K38/27, A61P19/00

Applicant
NEUREN PHARMACEUTICALS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2004/027187

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☒ in written format

   ☒ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☒ furnished subsequently to this Authority for the purposes of search.

3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-21
Industrial applicability (IA)	Yes:	Claims	1-21 (cf.text)
	No:	Claims	

2. Citations and explanations

see separate sheet

D1: WO 02/101002 A (GENODYSSEE; ESCARY, JEAN-LOUIS) 19 December 2002 (2002-12-19)
D2: US-B1-6 399 565 (ASADA NORIAKI ET AL) 4 June 2002 (2002-06-04)
D3: US-B1-6 417 237 (DADEY ERIC J ET AL) 9 July 2002 (2002-07-09)
D4: EP-A-0 916 345 (SUMITOMO PHARMACEUTICALS COMPANY, LIMITED) 19 May 1999 (1999-05-19)
D5: BOGUSZEWSKI C L ET AL: "Cloning of two novel growth hormone transcripts expressed in human placenta" JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, NEW YORK, NY, US, vol. 83, no. 8, August 1998 (1998-08), pages 2878-2885, XP002284559 ISSN: 0021-972X
D6: EP-A-0 587 427 (MITSUI TOATSU CHEMICALS, INC) 16 March 1994 (1994-03-16)

Item V:

1. D1 discloses the use of a 20kDa hGH-V (human growth hormone variant) polypeptide which is identical to peptide no.7 as used in the application for the treatment of growth hormone deficiency and of diseases/disorders associated with it. e.g. insulin resistance and retinopathy.

   D2 discloses discloses the use of 20kDa hGH-V (human growth hormone variant) polypeptides whose sequence is closely related to peptide no.7 as used in the application for the treatment of growth hormone deficiency and of diseases/disorders associated with it. The protein is said to have only a weak activity in inducing glucose intolerance.

   D3 discloses the use of hGH for the treatment of osteoporosis, kidney disease, hypertension and depression.

   D4 discloses the use of hGH for the treatment of anorexia.
   Documents D5 and D6 disclose the cloning and production, respectively, of the

20 kDa hGH-V protein.

2. Claim 1 is not novel vis-a-vis documents D1 or D2.
Claims 2-21 are not inventive in view of these documents (cf. also documents D3-D4 which relate to diseases/disorders treatable by hGH).

3. For the assessment of the present claims 1-21 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.